

Ethics of Complementary and Alternative Medicine Use in Children

Sunita Vohra, MD, MSc^{a,b,*},
Michael H. Cohen, JD, MBA^c

^a*Complementary and Alternative Research and Education (CARE) Program,
Stollery Children's Hospital, Edmonton, AB, Canada*

^b*Department of Pediatrics, Faculty of Medicine, 8213 Aberhart Centre #1,
11402 University Avenue, University of Alberta, Edmonton, AB T6G 2J3, Canada*

^c*Law Offices of Michael H. Cohen, 777 Massachusetts Avenue, PO Box 391108,
Cambridge, MA 02193, USA*

Complementary and alternative medicine (CAM) has enjoyed tremendous public interest in North America in recent years. Usage data confirm that CAM is sought by a broad section of society, including children and adolescents [1–4]. Breuner and colleagues [5] found that 70% of homeless youth (n = 157) reported CAM use, helping to dispel the myth that CAM use is exclusive to those who have greater disposable income. CAM use extends beyond ethnic stereotypes, although its use may be higher in immigrant families. For example, Lohse and colleagues [6] sampled 2562 caregivers and found that although 48.4% of Latino children used herbs, so did 31.4% of non-Latino children. Many of the ethical considerations regarding CAM use in the pediatric population are the same as those for conventional medicine.

CAM is used most often by those who have serious, chronic, or recurrent illness, sometimes for symptom control and sometimes to combat the primary disease. Others use CAM to promote wellness or as a prophylaxis. For example, in Canada, Hagen and colleagues [7] found that 64% of pediatric rheumatology patients (n = 141) reported using at least one form of CAM. These results were similar to a United States study of 503 children who had chronic illness, of whom 61.6% reported dietary supplement use

* Corresponding author. CARE Program, Department of Pediatrics, 8213 Aberhart Centre #1, 11402 University Avenue, Edmonton, AB T6G 2J3, Canada.

E-mail address: care@med.ualberta.ca (S. Vohra).

[8]. Rates of CAM use have approximated 50% in several studies conducted in pediatric emergency departments [3,9], suggesting that pediatric CAM use is common in general, although it may be even more so in specific subpopulations of children. Usage rates seem to vary widely across studies, depending on how CAM is defined, whether usage describes current versus lifetime exposure, the nature of the population under study, and the method of inquiry (eg, mailed survey versus interview).

A phenomenon led by the public, CAM has caught the attention of conventional medicine, including academic hospitals. Complementary therapies are increasingly being offered in conventional medical settings, and dedicated funding for CAM research has been created within the National Institutes of Health (NIH), primarily at the National Center for Complementary and Alternative Medicine (NCCAM) but also at various other centers and institutes such as the Office of Cancer Complementary and Alternative Medicine at the National Cancer Institute. This article explores the major ethical principles involved in pediatric CAM use and how they affect clinical care and research.

Ethical principles

According to the 2005 Institute of Medicine (IOM) report on CAM in the United States [10], the relevant ethical commitments or values that must be considered are (1) social commitment to public welfare, or beneficence; (2) duty of nonmaleficence; (3) respect for patient autonomy/consumer choice; (4) recognition of medical pluralism; and (5) public accountability. The legal and policy implications of pediatric CAM use are being explored in the peer-reviewed literature, providing additional perspectives for consideration [11–14]. An overarching theme that has emerged is that the same standards for evaluation of safety and efficacy should apply whether a therapy is labeled “conventional” or “CAM,” particularly because the label may change over time [10,15]. Furthermore, legal and ethical principles that apply to conventional medicine can, by and large, be applied across the board whether an emerging therapy is labeled “conventional,” “innovative,” or “CAM.”

Although the IOM framework forms the basis for this article, it is worth noting that these IOM “value commitments” reflect familiar values injected in a new way. More often, ethicists refer to autonomy, nonmaleficence, beneficence, and justice. The IOM, however, leaves out justice, perhaps rephrasing it in terms of public accountability, and adds a fifth value—medical pluralism—a valuable contribution in and of itself because it inherently validates the judicious inclusion of therapies that historically have been outside conventional clinical care.

Social commitment to public welfare (beneficence)

Health care providers have a duty of beneficence to the individual patient and to the public, which can be interpreted to mean that health care

providers are compelled to provide therapies based on best available evidence, regardless of whether the therapy is complementary, alternative, or conventional. According to the IOM, this commitment to public welfare translates into an obligation to generate and provide access to the best information available on the efficacy of CAM therapies to health care practitioners, policy makers, and the public [10].

To promote such access, a number of academic institutions have initiated “integrative” medicine programs, bringing complementary and conventional medicine together under one roof. A leading example is the Consortium of Academic Health Centers for Complementary and Integrative Medicine (CAHCIM) [16]. Launched in 1999, CAHCIM grew within 8 years to include 38 medical schools in the United States and Canada, with such notable institutions as Harvard, Yale, Duke, Stanford, and others. The primary mission for academic integrative medicine programs is to advance research, education, and clinical care in complementary and integrative therapies. Dedicated pediatric integrative medicine programs are also developing across the United States and Canada, as are pediatric CAM networks, to foster new research, education, and clinical initiatives [16–23]. These initiatives allow for academics and community providers (conventional and complementary) to come together to identify promising therapies, share knowledge, and exchange ideas due to their common social commitment to public welfare. A recent pediatrician survey acknowledges the relevance of these initiatives: 87% report being asked by patients or parents about CAM therapies, and 83% desired additional information or education about CAM [24]. CAM is of broad interest to families, making it important and relevant for conventional health care providers who wish to provide family-centered care. Consideration of the family’s values, beliefs, and preferences are part of acting in a child’s best interests and are therefore consistent with the ethical value of public accountability.

Nonmaleficence

Health care providers are duty-bound to protect their patients from harm. This obligation has multiple implications for clinical care and research as it relates to CAM: (1) there must be a commitment of resources and effort to identify harms; (2) such harms must be communicated to health care providers and the public in an efficient manner (effective knowledge translation becomes part of the ethical obligation of researchers); and (3) when harms are known, patients must be protected, suggesting that CAM can be abusive or neglectful when a known effective life-saving therapy is denied. Children who have life-threatening illness are also some of the highest users of CAM [25,26]. If choosing CAM denies the child access to a life-saving conventional therapy that has been proved effective, the courts may not take a lenient view of parental decision making that substitutes a CAM therapy with less evidence of efficacy. Although there are some

cases of judicial leniency for religious choice, courts do not favor abandoning necessary medical care. The selection of therapies based on religious grounds does not necessarily apply to the choice of nonstandard, CAM therapies because these therapies may involve value choices and personal judgments outside the religious domain [11]. Recent work also suggests that CAM therapies should ideally be “sensibly incorporated into a conventional treatment plan” [11]. Rather than forcing parents to choose between CAM and conventional medicine, it may be most helpful to allow them to chart a course that incorporates the best of both and to provide clinical guidance that allows them to draw meaningful conclusions. This integration is most easily done when the relative risks and benefits have been well delineated.

Safety research can be politically charged. Some CAM providers may believe it is unfair to scrutinize their field, examining it for potential harms. The IOM report on patient safety in conventional medicine [10] is a cautionary tale, demonstrating that patient safety is not necessarily assured by good intentions alone. Patient safety would be furthered if the CAM practitioner community were similarly willing to take a self-critical view to identify potential harms associated with its therapies and mitigate them accordingly. Such initiatives are beginning and need to be supported and encouraged [27–29]. Such research is not necessarily popular among all practitioners, yet these data are vital to ensure that preventable harms are identified and avoided.

Lack of adequate safety data can be a major obstacle when considering approaches recommended to pediatricians with regard to their patients’ CAM use. The pediatrician should “determine whether the CAM therapies selected are known to be unsafe and/or ineffective” [11]; however, one cannot make this determination when the primary data are lacking. Although it is not reasonable to assume that lack of harms reporting is equivalent to data confirming safety, it also is not reasonable to overestimate risk about therapies that have been used by millions of people over hundreds, even thousands, of years.

Because safety cannot be assumed, it seems that the best, most ethical course of action is to invest some energy into documenting safety. When this approach is taken, useful data are obtained, allowing health care providers to refer with greater ease and allowing patients to provide truly informed consent [28,29]. If the CAM therapy is safe, then patients, referring health care providers, policy makers, and other stakeholders can be reassured. If it is not safe, then it is better for all concerned to know this and to take appropriate steps to mitigate risk. Patient interests are not served when these issues are oversimplified: safety is relative, not absolute, and must be considered in combination with potential benefits; that is, how much risk is tolerable for how much potential benefit? There is no single “right” answer but one that each family and health care provider must come to terms with, given the individual circumstances of the specific child in question.

Patient autonomy

Respect for patient autonomy and consumer choice promotes the right of individuals to make free and informed decisions. Whether the therapy is conventional or CAM, such decisions need to be informed about risks and benefits [10].

Evidence about CAM therapies may be more challenging to accumulate, for a variety of reasons. Industry does not have the same financial incentive to invest in research due to difficulties in patenting natural remedies. If research is to be done, the burden often rests with public agencies such as the NIH NCCAM, the Canadian Institutes of Health Research, and publicly funded universities who ultimately serve the public, not their shareholders. Some may argue that this approach benefits the public good in a manner that industry research cannot. Others believe that this is a “waste” of taxpayer dollars, because they have already concluded that CAM is ineffective [30].

Even though CAM evidence may be more challenging to develop, health care providers need to be aware of current evidence with regard to CAM therapies and not to assume such evidence does not exist or is of inferior quality. Moher and colleagues [31] have identified more than 1400 pediatric CAM randomized controlled trials and more than 45 pediatric CAM systematic reviews. Although CAM research could benefit from improved methodological rigor, the quality of CAM randomized controlled trials and systematic reviews met or surpassed that of conventional medicine [32–34].

Respect for patient autonomy and consumer choices demands open discussion and shared decision making, whereby the patient can be presented with the best available evidence, regardless of whether the therapy is conventional or complementary. Liability might be premised on the theory of failed informed consent if clinicians fail to raise reasonable feasible alternatives or ignore evidence supporting the efficacy of integrating complementary therapies [12,35]. At present, only half of pediatricians agree that “pediatricians should consider use of all potential therapies, not just those of mainstream medicine, when treating patients” [24]. There is room for improvement in our evidence-based era when we strive to provide family-centered care, but how can we do that if pediatric health care providers are not yet prepared to take the family’s preferences and values into consideration?

The few instances in which courts have been involved support this framework. United States courts are generally reluctant to overrule parental decisions about treatment, except in life-threatening situations [12]. A few courts have supported parental choices for CAM therapies when supported by some medical authority, as long as the child’s life was not in danger [12].

Issues of autonomy are made even more complex when there is conflict between the child’s wishes and those of the parents. The developing autonomy, values, and independence of children and adolescents implies that as children mature, they are owed not only confidentiality and privacy but also respect for treatment decisions [36].

Recognition of medical pluralism

The IOM report recognizes medical pluralism, as it honors social pluralism, acknowledging that many forms of achieving health and healing exist in the world. This principle implies a moral commitment to openness and a commitment to innovative ways of finding evidence [10]. This approach is very much in keeping with current moves in medicine to ensure that health care providers demonstrate cultural competency [37–39]. There is a need to respect individual and cultural differences and to consider the effect of socio-cultural-religious beliefs on health care practices. The World Health Organization estimates that 80% of the world's population uses CAM, not conventional medicine, as first-line therapy [40]. Given today's "global village," including the presence of large immigrant populations, health care providers must recognize that their patients may use many approaches to achieve health. Asking about CAM use in an open, nonjudgmental fashion should be incorporated into routine history taking for all patients at every visit.

Public accountability

Because health care and health care research are publicly funded, it seems reasonable that CAM, in the context of clinical and research issues, should be held publicly accountable. This thinking raises many important yet complex issues: Who can own knowledge of indigenous traditions? Who should own such knowledge? Under what circumstances should this knowledge be transferred, developed, commercialized, or maintained as private (or in some traditions, held as sacred, and thereby beyond public dissemination?) [10]. Aboriginal peoples have rarely been consulted about the commercialization of their traditional knowledge, nor have they necessarily benefited from it. An example of this is the current marketing of traditional plant medicines [41]. Many aboriginal people consider this marketing an exploitation of traditional knowledge at the hands of European settlers because it is sometimes used without any form of compensation [42]. As a result of the mistrust built from such research methods, Aboriginal peoples have struggled with ownership over their own knowledge, practices, and bodies. These barriers must be acknowledged and overcome. It is fortunate that this important work is starting to be done and that guidelines for ethical research involving Aboriginal people have been developed [41,43,44]. These approaches to promote public accountability and respectful collaboration might be relevant in a broader context for the interaction between conventional Western medicine and CAM because the basis for many CAM therapies may be grounded in other cultures.

Public accountability may be most important in vulnerable populations, including children. An ethical approach must include values such as trust and respect for different social and cultural perspectives; therefore, health care systems must find ways to recognize and accommodate different views while providing responsible advice and treatment [36]. Because the health care system is accountable to the public that funds it, it must satisfy that it

is meeting the best interests of its patients. As discussed earlier, this standard should be informed by the best available evidence, which may include conventional, complementary, or integrative approaches.

Impact on clinical care and research

Clinical care

Perhaps the greatest challenge with regard to ethical approaches to including CAM in conventional settings is the overall lack of policies within health care institutions [11]. Some model guidelines are provided by the Federation of State Medical Boards for physician use of CAM therapies in medical practice, including criteria for discipline, guidelines to evaluate patients and treatment plans, documentation of medical records, and sale of goods from physician offices [45]. These guidelines, however, do not necessarily address institutional concerns such as how to handle inpatient desire to continue the use of dietary supplements.

It is important to consider that most families use CAM in conjunction with conventional care, not instead of it [46]. It then becomes imperative for pediatric health care providers to (1) ask questions regarding CAM use (to promote open discussion, preferably in nonjudgmental fashion, else families will not disclose use); (2) become knowledgeable about CAM therapies; (3) refer to a pediatric integrative medicine specialist if they lack this expertise (such expertise is now increasingly available); and (4) develop a communications strategy with their patients' CAM providers. Communicating with CAM providers does not necessarily imply referral or approval of a given therapy; rather, in the patient's best interests, an "integrative" approach—whereby each provider knows the care plan of the other, coordinating their efforts and minimizing potential interactions—seems preferable to the "dis-integrative" approach whereby the patient is abandoned to chart his or her course alone while the health care providers knowingly and willfully choose not communicate. According to Adams and colleagues [14], a careful balance must be constructed, such that health care providers are encouraged to provide continuity of care through their legal and ethical obligation of nonabandonment while avoiding the false perception that remaining in the relationship provides reassurance to the patient about his or her health care decisions (ie, health care providers should not unduly overemphasize their ongoing role if their patient has made choices with full awareness of the possible consequences). Patient safety also demands open communication, suggesting that patients might benefit if conventional care practitioners were more willing to engage in dialog with CAM counterparts about different diagnostic and therapeutic methods.

Adams and colleagues [14] suggested seven factors that should be considered when assessing the ethics of whether to offer CAM therapies: (1) severity and acuteness of illness; (2) curability with conventional treatment; (3)

risks of conventional treatment (eg, invasiveness, adverse effects); (4) evidence with regard to the safety and efficacy of the proposed CAM therapy (including assessment of quality of the evidence); (5) degree of understanding regarding the risks/benefits of conventional and CAM therapies; (6) acceptance of those risks (by the patient); and (7) persistence of the patient's intention to use CAM therapy. A risk/benefit approach to guide therapeutic decision making is a useful construct for patients and health care providers [15].

Principles of social justice are challenged by the lack of access to CAM therapies demonstrated to be safe and effective. Lack of access and lack of coverage pose major barriers, creating a tiered health care system that serves the needs of some better than others.

Research

The relative lack of funding for CAM research in comparison to funding spent on pharmaceutical research has been a cause of debate. Some believe that publicly funded institutions have a moral responsibility to fund research according to the priorities of the public they serve. Others argue that investigating CAM is unethical because it wastes public resources on therapies of little value [30]. Certainly, CAM research is relevant to the public, and important questions of efficacy and safety remain that demand answers if patient needs are to be met. Such research must be conducted in a collaborative and respectful fashion.

Summary

The ethics of CAM use is founded in principles of beneficence, nonmaleficence, and autonomy to which the IOM has added medical pluralism and public accountability. There is an urgent and compelling case for research to evaluate the safety and efficacy of pediatric therapies and for clinical practice to adopt the best available evidence, whether the therapy under consideration is conventional, complementary, alternative, or integrative. Safety and efficacy are relative and must be interpreted in light of a child's health state and the family's beliefs, values, and preferences. An ethical approach to the pediatric use of CAM is a complex, multifaceted issue that demands open communication between families and all their health care providers to meet the best interests of the child.

Acknowledgments

The authors gratefully acknowledge the contributions and thoughtful advice provided by Sheena Sikora, Connie Winther, Lynne Lacombe, Cecelia Bukutu, Pierre Haddad, Liz Estey, and Daniel Roth.

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